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EXAMINER

STRZELECKA, TERESA E

ART UNIT PAPER NUMBER

1637

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/642,068

Applicant(s)

STUELPNAGEL ET AL.

Examiner

Teresa E. Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10,27-31 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-10,27-31 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/8/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to an amendment filed September 8, 2006. Claims 2-10, 27-31, 33-37 were previously pending. Applicants did not amend any claims.
2. Applicants' arguments obviated the following rejections: rejection of claims 2, 5-9, 27-31 and 33-37 under 35 U.S.C. 102(e) as being anticipated by Kuimelis et al. (U.S. patent No. 6,537,749 B2) as evidenced by Lashkari et al.; rejection of claims 2-10, 27-31 and 33-37 under 35 U.S.C. 103(a) over Holmes and Beattie.
3. This office action is made non-final because of new grounds for rejection.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on September 8, 2006 was filed after the mailing date of the non-final office action on March 8, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim interpretation

5. The following interpretation of claim limitations is used to evaluate correspondence between the current claims and prior art:
 - A) Applicants defined the term "pool" in the following way (page 8, last paragraph):
"By "pool" is meant a plurality or more than one solution-phase oligonucleotide."
 - B) The term " first and second linkers" is interpreted as linkers which may be the same, as there is no requirement that they have to be different.
 - C) The term "chip" in claim 29 is interpreted as any substrate (it is used interchangeably with "substrate" in the claim. Applicants' definition on page 16, fourth paragraph: "... By "chip" or

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biochip" herein is meant a planar substrate to which nucleic acids are directly or indirectly attached."

D) Applicants did not define the term "array" therefore any arrangement of oligonucleotides bound to a solid support is considered to be an array.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 2, 5-10, 27-31 and 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Lipshutz et al. (U.S. Patent No. 6,013,440 A) as evidenced by Sinha et al. (Nucl. Acids Res., vol. 12, pp. 4539-4557).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Since claim 29 is specie of claims 27 and 30 and claims 33 and 35 are restated versions of claim 27, and claims 28 and 34 differ from claim 29 by the support being beads, only steps of claim 29 are discussed explicitly.

Regarding claims 27-30 and 33-35, Lipshutz et al. teach multiplex detection of target nucleic acids, the method comprising:

a) providing an array comprising a substrate and a population of oligonucleotides, said population comprising at least first and second subpopulations, wherein said first subpopulation comprises at least a first oligonucleotide and, wherein said second subpopulation comprises at least a second oligonucleotide, wherein said first oligonucleotide is different from said second oligonucleotide and, wherein said first and second oligonucleotides are of known sequence, said first and second oligonucleotides being immobilized directly to said substrate through first and second cleavable linkers, respectively (Fig. 1; col. 2, lines 16-37 and 59-62; col. 3, lines 18-35; col. 6, lines 20-48; col. 21, lines 4-33);

b) cleaving said first and second linkers, thereby releasing said first and second subpopulations from said substrate thereby generating a pool of oligonucleotides comprising said first and second oligonucleotides (col. 2, lines 59-62; col. 21, lines 4-33); and

c) contacting said first and second oligonucleotides with a composition comprising at least a first and second target nucleic acid, whereby said first and second target nucleic acids hybridize with said first and second oligonucleotides whereby said target nucleic acids are detected (col. 2, lines 24-26; col. 3, lines 46-67; col. 4, lines 1-67; col. 5, lines 1-23; col. 7, lines 34-42; col. 8, lines 12-67; col. 9, lines 1-67; col. 10, lines 1-13).

Regarding claims 8, 28 and 34, Lipshutz et al. do not specifically teach the substrate being beads. However, they teach synthesis of oligonucleotides on controlled pore glass (CPG) (col. 21,

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line 7) and synthesis by the method of Sinha et al. (col. 20, lines 24, 25). Sinha et al. teaches synthesis of oligonucleotides on CPG beads (page 4544, last paragraph). Therefore, by teaching synthesis of oligonucleotides by the method of Sinha et al. Lipshutz et al. inherently teach synthesis on glass beads.

Regarding claim 2, Lipshutz et al. teach oligonucleotides with known sequences (col. 2, lines 18-22).

Regarding claims 5 and 31, Lipshutz et al. teach covalent attachment of oligonucleotides to the substrate (col. 17, lines 57-67; col. 18, lines 1-9; col. 21, lines 4-33).

Regarding claims 6 and 9, Lipshutz et al. teach synthesizing the oligonucleotides on a substrate (col. 16, lines 47-67; col. 17-19).

Regarding claim 7, Lipshutz et al. teach a substrate with a discrete sites (col. col. 16, lines 47-66).

Regarding claim 10, Lipshutz et al. teach printing and photolithography (col. 17, lines 18-67; col. 18-19).

Regarding claim 36, Lipshutz et al. teach glass (col. 17, lines 57, 58).

Regarding claim 37, Lipshutz et al. teach a chip (col. 17, lines 13-16 and 57-60).

8. Claims 2, 5-7, 9, 27, 30, 31, 33 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Lam et al. (U.S. Patent No. 5,650,489 A).

Claims 27, 30, 33 and 35 are similar in scope, therefore they will be considered in claim 27.

Regarding claims 27, 30, 33 and 35, Lam et al. teach multiplex detection of target nucleic acids, the method comprising:

a) providing a substrate comprising at least first and second different oligonucleotides linked to said substrate through first and second cleavable linkers, respectively (col. 4, lines 60-67; col. 5, lines 1-17 and 34-41; col. 6, lines 41-53; col. 16, lines 10-40);

b) cleaving said first and second linkers, thereby releasing said first and second oligonucleotides from said substrate thereby generating a pool of oligonucleotides comprising said first and second different oligonucleotides (col. 20, lines 66, 67; col. 21, lines 1-24; col. 22, lines 24-53); and

c) contacting said first and second oligonucleotides with a composition comprising at least a first and second target nucleic acid, whereby said first and second target nucleic acids hybridize with said first and second oligonucleotides whereby said target nucleic acids are detected (col. 17, lines 8-16; col. 20, lines 19-38; col. 23, lines 57-64).

Regarding claim 2, Lam et al. teach oligonucleotides comprising a known sequence (col. 16, lines 41-46)

Regarding claims 5 and 31, Lam et al. teach covalently attached the oligonucleotides to the substrate through linkers (col. 14, lines 31-67; col. 15, lines 57-67; col. 16, lines 1-40).

Regarding claims 6 and 9, Lam et al. teach synthesizing the oligonucleotides on a substrate (col. 14, lines 31-67; col. 15, lines 39-46).

Regarding claim 7, Lam et al. teach discrete sites on the support (col. 4, lines 64-67; col. 5, lines 1-9).

Regarding claims 36 and 37, Lam et al. teach glass, plastic, silica (col. 39, lines 39-46).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (U.S. Patent No. 6,013,440 A), as evidenced by Sinha et al. (Nucl. Acids Res., vol. 12, pp. 4539-4557), and Nelson et al. (Nucl. Acids Res., vol. 20, pp. 6253-6259 (1992)).

A) Lipshutz et al. teach fluorescence detection of hybrids (col. 25, lines 43-46), but do not teach labeling of the synthesized oligonucleotides.

B) Regarding claims 3 and 4, Nelson et al. teach labeling oligonucleotides during the synthesis step using labeled phosphoramidites (Abstract; page 6255, last paragraph; page 6256, paragraphs 1-5; Table 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have labeled the oligonucleotides of Lipshutz et al. using the method of Nelson et al. The motivation to do so, provided by Nelson et al., would have been that the oligonucleotides were used directly in PCR amplification and quantitation, mRNA isolation, FISH analysis, antisense gene regulation, DNA fragment analysis and triple helix formation (page 6258, last paragraph).

11. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka
11/7/06